CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Medical Policy (HFD-040)
Robert Temple, MD
301-594-6758
Deputy Director
Rachel Behrman, MD, M.Ph
- Div Scientific Investigations
- Div of Drug Marketing, Advertising and Communication

Office of the Center Director (HFD-001)
Janet Woodcock, MD
301-594-5400
Deputy Director
Steven Galson, MD

Controlled Substance Staff
Deborah Leiderman, MD
Associate Director for Policy
Jane Axelrad

EEO/Recruitment Staff
Diane Smith (Actg)

Office of Counter Terrorism and Pediatric Drug Dev (HFD-950)
Dianne Murphy, MD
301-827-7777
Deputy Director
Rosemary Addy
- Division of Pediatric Drug Dev
- Division of Counter-Terrorism

Office of Executive Programs (HFD-006)
Deborah Henderson
301-594-6779
Deputy Director
Khyati Roberts
- Executive Operations Staff
- Review Standards Staff
- Advisors and Consultants Staff
- International Program
- Information Management Program
- Ombudsman

Office of New Drugs (HFD-020)
John Jenkins, MD
301-594-3937
Deputy Director
Sandra Kweder
- Pharmacology/Toxicology Staff
- Program Management Team
- Study Endpoints and Labeling Team
- Pregnancy Labeling Team
- Guidance Policy Team
- Regulatory Affairs Team

Office of Pharmacoepidemiology and Statistical Science (HFD-001)
Paul Seligman, MD
301-827-6276
Deputy Director
Vacant

Office of Management (HFD-010)
Russell Abbott
301-594-6741
Deputy Director
Paula Bourkland
- Div of Management and Budget
- Div of Management Services

Office of Regulatory Policy (HFD-005)
Jane Axelrad
301-594-5400
- Div of Regulatory Policy I
- Div of Regulatory Policy II
- Div of Information Disclosure Policy

Office of Pharmaceutical Science (HFD-003)
Helen N. Winkle
301-594-2847
Deputy Director
Ajaz S. Hussain, PhD
- Informatic Computational Safety Analysis
- Process Analytical Technologies
- Quality Implementation Staff
- New Drug Microbiology Team

Office of Drug Evaluation I (HFD-101)
Robert Temple, MD (Actg)
301-594-6758
Deputy Director
Rachel Behrman, MD, M.Ph (Actg)
- Div of Neuropharmacological Drug Products
- Div of Oncology Drug Products
- Div of Cardio-Renal Drug Products

Office of Drug Evaluation III (HFD-103)
Florence Houn, MD
301-827-3144
Deputy Director
Julie Beitz, MD
- Div of Gastrointestinal and Coagulation Drug Products
- Div of Reproductive and Urologic Drug Products
- Div of Medical Imaging and Radiopharmaceutical Drug Products

Office of Drug Safety (HFD-400)
Victor Raczkowski, MD
301-827-3219
Deputy Director
Anne Trontell, MD
- Div of Surveillance, Research, & Comm Support
- Div of Medication Errors & Tech Support
- Div of Drug Risk Evaluation

Office of Biostatistics (HFD-700)
Robert O'Neill, PhD
301-827-3195
Deputy Director
Charles Anello, ScD
- Quantitative Methods & Research Staff
- Division of Biometrics I
- Division of Biometrics II
- Division of Biometrics III

Office of Training and Communications (HFD-200)
Nancy Smith, PhD
301-827-1651
Deputy Director
John Friel
- Div of Training and Development
- Div of Drug Information
- Div of Library and Info Services
- Div of Public Affairs

Office of Compliance (HFD-300)
David J. Horowitz
301-827-8910
Deputy Director
Betty L. Jones
- Div of New Drugs and Labeling Compliance
- Div of Manufacturing and Product Quality
- Div of Compliance Risk Mgmt and Surveillance

Office of Information Technology (HFD-070)
Linda Burek
301-827-6240
Deputy Director
Margo Burnette
- Quality Assurance Staff
- Technology Support Services Staff
- Div of Infrastructure Management and Services
- Div of Applications Development Services

Office of Biotechnology Products (HFD-003)
Yuan-yuan Chiu, PhD (Actg)
301-594-2847
- Div of Monoclonal Antibodies
- Div of Therapeutic Proteins

Office of New Drug Chemistry (HFD-800)
Moheb M Nasr, PhD (Actg)
301-827-5918
Deputy Director
Charles Hoiberg, PhD
- Div of New Drug Chemistry I
- Div of New Drug Chemistry II
- Div of New Drug Chemistry III

Office of Clinical Pharmacology and Biopharmaceutics (HFD-850)
Lawrence Lesko, PhD
301-594-5690
Deputy Director
Shiewmei Huang, PhD
- Div of Pharmaceutical Evaluation I
- Div of Pharmaceutical Evaluation II
- Div of Pharmaceutical Evaluation III

Office of Generic Drugs (HFD-600)
Gary Buehler
301-827-5845
Deputy Director
Robert West, R.Ph
- Div of Bioequivalence
- Div of Chemistry I
- Div of Chemistry II
- Div of Chemistry III
- Div of Labeling and Program Support

Office of Testing and Research (HFD-900)
Ajaz Hussain, PhD (Actg)
301-827-5917
Deputy Director
Vacant
- Lab. of Clinical Pharmacology
- Div of Applied Pharmacology Research
- Div of Pharmaceutical Analysis
- Div of Product Quality Research

Office of Drug Evaluation II (HFD-102)
Robert Meyer, MD
301-827-5920
- Div of Pulmonary Drug Products
- Div of Metabolic and Endocrine Drug Products
- Div of Anesthetic, Critical Care and Addiction Drug Products

Office of Drug Evaluation IV (HFD-104)
Mark Goldberger, MD
301-827-2350
Deputy Director
Edward Cox, MD
- Div of Anti-Infective Drug Products
- Div of Anti-Viral Drug Products
- Div of Special Pathogen and Immunologic Drug Products

Office of Drug Evaluation V (HFD-105)
Jonca Bull, MD
301-827-2250
Deputy Director
Brian Harvey, MD, PhD
- Botanical Review Team
- Div of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products
- Div of Over-The-Counter Drug Products